

Cardoso, Esperanca

From: D'Amico, Louis
Sent: Tuesday, March 21, 2017 10:23 AM
To: Bahadori, Tina; Jones, Samantha; Ross, Mary
Cc: Thayer, Kris
Subject: RE: ACC

Louis D'Amico, Ph.D.
Assistant Center Director for Communications and Regulatory Support (Acting)
U.S. EPA, ORD/NCEA
damico.louis@epa.gov
O: (703) 347-0344 M: (703) 859-1719

From: Bahadori, Tina
Sent: Tuesday, March 21, 2017 10:22 AM
To: Jones, Samantha <Jones.Samantha@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Cc: D'Amico, Louis <DAmico.Louis@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: RE: ACC

From: Jones, Samantha
Sent: Tuesday, March 21, 2017 10:20 AM
To: Ross, Mary <Ross.Mary@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: Re: ACC

Sent from my iPhone

On Mar 21, 2017, at 10:18 AM, Ross, Mary <Ross.Mary@epa.gov> wrote:

OK, will follow up. Crystal asked me to cancel her leave for this week so I think she's here and forgot to change the message.

From: Bahadori, Tina
Sent: Tuesday, March 21, 2017 10:06 AM
To: Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: ACC

Let's please:

- 1) Mary, I know Crystal is out today. Can you please prompt James/everyone to respond to the FOIA data call today so that Crystal can wrap it up asap when she is back? We need some balance in the narrative.
- 2) Let's get that response letter out asap too. I am going to look at the last version – I assume it's the one from Samantha?

T.

From: Jones, Ashley

Sent: Tuesday, March 21, 2017 9:30 AM

To: Alexander, Laurie <Alexander.Laurie@epa.gov>; Avery, James <Avery.James@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Bateson, Thomas <Bateson.Thomas@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; Blessinger, Todd <blessinger.todd@epa.gov>; Boone, Amanda <Boone.Amanda@epa.gov>; Branigan, Melissa <branigan.melissa@epa.gov>; Brinkerhoff, Chris <Brinkerhoff.Chris@epa.gov>; Buckley, Barbara <Buckley.Barbara@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Cai, Christine <Cai.Christine@epa.gov>; Chen, Anna <chen.anna@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Congleton, Johanna <congleton.johanna@epa.gov>; Corona, Elizabeth <Corona.Elizabeth@epa.gov>; Cubbison, Christopher <cubbison.chris@epa.gov>; CURTIS, LUCY <Curtis.Lucy@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Dean, Jeffry <Dean.Jeffry@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Dishaw, Laura <Dishaw.Laura@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Euling, Susan <Euling.Susan@epa.gov>; Field, Malcolm <Field.Malcolm@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>; Frithsen, Jeff <Frithsen.Jeff@epa.gov>; Fritz, Jason <Fritz.Jason@epa.gov>; Galizia, Audrey <Galizia.Audrey@epa.gov>; Gamble, Janet <Gamble.Janet@epa.gov>; Gatchett, Annette <Gatchett.Annette@epa.gov>; Gibbons, Catherine <Gibbons.Catherine@epa.gov>; Gift, Jeff <Gift.Jeff@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Grambsch, Anne <Grambsch.Anne@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Hogan, Karen <Hogan.Karen@epa.gov>; Horansky, Alex <Horansky.Alex@epa.gov>; Hotchkiss, Andrew <Hotchkiss.Andrew@epa.gov>; Hutchins, Debra <Hutchins.Debra@epa.gov>; Itkin, Cheryl <Itkin.Cheryl@epa.gov>; Jarabek, Annie <Jarabek.Annie@epa.gov>; Jinot, Jennifer <Jinot.Jennifer@epa.gov>; Johnson, Maureen <Johnson.Maureen@epa.gov>; Jones, Ashley <Jones.Ashley@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Kadry, Abdel-Razak <Kadry.Abdel@epa.gov>; Kelley, Dave <Kelley.Dave@epa.gov>; Keshava, Nagalakshmi <Keshava.Nagu@epa.gov>; Kopylev, Leonid <Kopylev.Leonid@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Lee, Janice <Lee.JaniceS@epa.gov>; Li, Jenny <Li.Jenny@epa.gov>; Lin, Yu-Sheng <Lin.Yu-Sheng@epa.gov>; Long, Tom <Long.Tom@epa.gov>; Luke, April <Luke.April@epa.gov>; Makris, Susan <Makris.Susan@epa.gov>; Matthews, Evangela <matthews.evangel@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Murphy, Patricia <Murphy.Patricia@epa.gov>; Newhouse, Kathleen <Newhouse.Kathleen@epa.gov>; Owens, Beth <Owens.Beth@epa.gov>; Pardo, Larissa <Pardo.Larissa@epa.gov>; Park, Junyong <park.junyong@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; Persad, Amanda <Persad.Amanda@epa.gov>; Petersen, Dan <Petersen.Dan@epa.gov>; Pratt, Margaret <pratt.margaret@epa.gov>; Preuss, Peter <Preuss.Peter@epa.gov>; Radke-Farabaugh, Elizabeth <radke-farabaugh.elizabeth@epa.gov>; Nachman, Rebecca <nachman.rebecca@epa.gov>; Reid, Jon <Reid.Jon@epa.gov>; Rieth, Susan <Rieth.Susan@epa.gov>; Ross, Christine <Ross.Christine@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Rutigliano, Marian <Rutigliano.Marian@epa.gov>; Salazar, Matt <Salazar.Matt@epa.gov>; Sams, Reeder <Sams.Reeder@epa.gov>; Samuels, Crystal <Samuels.Crystal@epa.gov>; Sanchez, Janice <Sanchez.Janice@epa.gov>; Sanchez, Yolanda <Sanchez.Yolanda@epa.gov>; Sasso, Alan <Sasso.Alan@epa.gov>; Schappelle, Seema <Schappelle.Seema@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Segal, Deborah <Segal.Deborah@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Shaw, Denice

<Shaw.Denice@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Solomon, Sarah <Solomon.Sarah@epa.gov>; Soto, Vicki <Soto.Vicki@epa.gov>; Spassova, Maria <Spassova.Maria@epa.gov>; Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>; Suter, Glenn <suter.glenn@epa.gov>; Tewolde, Salina <tewolde.salina@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Troyer, Michael <Troyer.Michael@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Vulimiri, Suryanarayana <Vulimiri.Sury@epa.gov>; Walker, Teneille <Walker.Teneille@epa.gov>; Wang, Lily (Lihong) <wang.lily@epa.gov>; Weaver, Andre <Weaver.James@epa.gov>; White, Paul <White.Paul@epa.gov>; Woodall, George <Woodall.George@epa.gov>; Wright, Michael <Wright.Michael@epa.gov>; Zwyer, Bette <zwyer.bette@epa.gov>

Subject: News Update: ACC Urges EPA To Weigh New Formaldehyde Data For Risk Assessment (Inside EPA)

ACC Urges EPA To Weigh New Formaldehyde Data For Risk Assessment

March 20, 2017

The American Chemistry Council (ACC) is urging EPA to consider what it calls new "game changing" research on formaldehyde's potential to cause leukemia before the agency finalizes a long-running assessment of the common chemical's public health risks, raising concerns that the agency has stopped considering the new data before the analysis is completed.

EPA has spent the past six years reworking a draft Integrated Risk Information System (IRIS) [assessment of formaldehyde](#) after a 2011 National Academy of Sciences (NAS) report criticized the agency's draft assessment and faulted IRIS procedures generally. The agency's last public draft of the assessment relies on a controversial 2010 study, known as the Zhang study, to conclude that exposure to formaldehyde could cause leukemia. The National Toxicology Program and the International Agency for Research on Cancer have reached similar conclusions.

Industry has long criticized the study, arguing that it has not been replicated, that its findings are unique and implausible, without a biological explanation.

In [a March 7 letter](#) to Tina Bahadori, director of EPA's National Center for Environmental Assessment, which oversees the IRIS program, ACC reiterates its concerns that EPA is continuing to rely on the Zhang study and is ignoring newer research "that further calls into question any causal association between formaldehyde exposure and [acute myeloid leukemia (AML)] or other lymphohematopoietic malignancies."

Bahadori assured ACC during a Feb. 21 meeting that the formaldehyde IRIS assessment has been substantially revised to incorporate new scientific evidence generated since 2010 and that all of the NAS recommendations have been addressed and incorporated, the letter says. But ACC remains "concerned that the revised formaldehyde IRIS assessment might not achieve an acceptable level of scientific rigor," the letter says.

The chemical industry group says it was surprised to learn that the "stopping rule" for the assessment has already been invoked, meaning the agency has set a fixed date when IRIS staff cease performing regular literature searches for new studies relevant to an IRIS assessment, and will instead only add to the assessment those new studies that would alter its conclusions.

Bahadori's immediate predecessor, Ken Olden, developed the stopping rule process as part of his efforts to make assessments move more efficiently through the IRIS pipeline.

ACC's Concerns

"We are disappointed in the continued lack of transparency by the Agency on how and when the stopping rules are applied and the Agency's lack of commitment to using a weight of evidence approach for chemical assessments," ACC writes. "As such, ongoing research and research currently undergoing peer review may be arbitrarily and inappropriately excluded from the assessment."

The letter includes an appendix referencing nearly two dozen studies that ACC says it believes are "game-changing" (i.e., critical to the revised formaldehyde IRIS assessment) and they must be reviewed for pertinence and impact on the assessment's conclusions."

ACC calls on EPA to perform a critical systematic review of all the data included in the formaldehyde IRIS assessment, including the research listed in ACC's appendix, before any revised formaldehyde IRIS assessment undergoes external review.

"We believe that a revised formaldehyde IRIS assessment that fails to reflect a transparent weight of evidence assessment that fully and critically evaluates and integrates evidence from studies published since the release of the 2010 draft assessment, will not be scientifically robust and may include erroneous conclusions," the letter says, referencing NAS' recommendation that a systematic review is needed to support a weight of evidence approach.

Among the newer research ACC highlights is a 2015 scientific publication re-examining the data underlying the Zhang study that concluded the data did not demonstrate a statistically significant association between formaldehyde and AML; recent scientific publications indicating significant methodological limitations of the Zhang study; and a series of published, peer-reviewed studies that "demonstrated conclusively that environmental (or exogenous) formaldehyde that is inhaled or ingested does not reach the bone marrow (where transformations giving rise to leukemia occur). These studies clearly call into question the biological plausibility of a causal connection between exogenous formaldehyde exposure and leukemia," ACC says. -- *Lara Beaven*